

REMARKS

This Amendment is to the final Office Action mailed June 28, 2004. Claims 1 to 35, 38 to 73 and 95 to 115 were pending previously in this application. Claims 36, 37 and 74 to 94 were previously withdrawn from consideration. Claims 9, 30, 49, 59, 67, 72, 98, 102, 109 and 114 have previously been canceled without prejudice or disclaimer. Claims 29, 31 to 35, 44 to 48, 50 to 58, 60, 61, 99 to 101, 103 to 108, 110 to 113 and 115 have been allowed. Claims 1 to 8, 10 to 16, 18, 20 to 28, 38 to 43, 62 to 66, 68 to 71, 73 and 95 to 97 stand rejected. Claims 17 and 19 have been objected to but would be allowed if amended to include all base game limitations. Claims 25, 38, 62, 69 and 95 have been amended herein.

In the Office Action, Claims 1, 3 to 8, 10 to 16, 18 and 20 to 24 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,656,146 to Clayman et al. ("*Clayman*"). Claims 25 to 28, 38 to 43, 62 to 66, 68 to 71, 73 and 95 to 97 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,543,087 to Sommercorn et al. ("*Sommercorn*"). Claim 2 was rejected under 35 U.S.C. § 103(a) as being obvious in view of *Clayman* and U.S. Patent No. 5,057,075 to Moncrief et al. ("*Moncrief*").

Regarding the rejection of Claims 1, 3 to 8, 10 to 16, 18 and 20 to 24 in view of *Clayman*, Applicants respectfully traverse that rejection. In particular, *Clayman* does not teach an external patient portion as recited in Claim 1. Viewing Figs. 1 and 2 of the present application, it is clear that the external patient portion 50 discussed in the present specification is located outside of the patient's body when implanted. Such configuration gives rise to the name "external patient portion". The stent of *Clayman* does not include, teach or suggest an external patient portion. Indeed, Figs. 5A and 8 show clearly that the stent of *Clayman* is inserted between the patient's renal pelvis area and patient's bladder. The purpose of the *Clayman* invention is described in the Background of the Invention section at column 1, beginning at line 17, wherein it is discussed that ureteral stents assist in urinary drainage from the kidney to the bladder of the patient. For at least the reason that *Clayman* does not teach or suggest the external patient portion recited in Claim 1, Claim 1 is patentably distinct over *Clayman*.

Additionally, *Clayman* does not specifically teach a second lumen extending through the tube from a second lumen port in an external patient portion to a second lumen port in an implantable portion, wherein the second lumen port and the implantable portion are spaced away from a curved segment, as recited in Claim 1. As discussed above, *Clayman* does not teach the external patient portion and therefore cannot teach a lumen extending from such external patient portion.

Moreover, the second lumen described briefly at column 3, line 35 of *Clayman* discusses that the bladder end region of the tubular segment may include two lumens, a main urine-transporting lumen and a bladder lumen to encase a suture, so that the suture does not become encrusted. Thus the bladder lumen does not appear to be provided for the purpose of transporting fluid, rather it is meant to house and protect suture material. Thus there is no indication that the second lumen of *Clayman* would have a second port in the implantable portion.

Also, there is no teaching or suggestion that a second lumen port, which does not appear to be taught, would be located in the implantable portion but spaced away from a curved segment. That is, besides an opening occurring at point B in Fig. 5A in *Clayman*, which is inside the body and not placed at an external portion of the stent, there is no hint or suggestion of where a second port, if provided, would be located. One may speculate that the second lumen would have a second port spaced away from the opening at point B, but this is speculation not teaching. Further, one would also have to assume that the second port is spaced away from a curved segment of the *Clayman* stent, which is located in the kidney portion of Fig. 5A. Again, this assumption not teaching. For at least this additional reason *Clayman* is deficient as a teaching. Applicants therefore respectfully submit that Claim 1 and Claims 2 to 8 and 10 to 15 that depend from Claim 1 are each in condition for allowance.

Claim 16 is patentably distinct over *Clayman* for at least some of the reasons discussed in connection with Fig. 1. For example, there appears to be no teaching or suggestion by *Clayman* to place a patient inflow section in between a connection section of the catheter and a separation section of the catheter, which is substantially straight when in an unstressed condition. The separation section spaces apart the patient inflow and patient outflow sections. Thus if the holes at the end of the stent of *Clayman* are taken to be the patient outflow opening of the patient outflow section of

Claim 16, there is no structure in *Clayman* corresponding to the patient inflow section which is spaced apart from the patient outflow section by a separation section. One must remember that according to Claim 16, the patient inflow opening in the patient inflow section is an implanted opening for the patient inflow lumen. The patient inflow lumen also communicates with an inflow port located at a proximal or non-implanted end of the catheter at the connection section. In short, Claim 16 specifies two lumens each having a proximal hole and an implantable hole. One of the lumens of *Clayman* on the other hand appears to have a closed end, which does not meet the Claim 16. For at least this reason, *Clayman* does not teach or suggest each of the elements of Claim 16. Accordingly, Applicants respectfully submit that Claim 16 and Claims 17 to 24 that depend from Claim 16 are each in condition for allowance.

Claims 25, 38, 62, 69 and 95 have each been amended and are as presently presented patentably distinct over *Sommercorn*. Those claims recite the physical distinction between the present invention and *Sommercorn* in that the fluid openings 56 of the present invention are located closer to an implantable cuff section of the catheter than are the holes 56 located with respect to distal openings 76. As has been described in detail in previous responses, one of the main advantages of the catheter of the present invention is that it provides enhanced coverage between the dialysis solution exiting one of the holes 56 or 76 with the patient's peritoneum, wherein the dialysate returns through the other of the holes 56 or 76. As has been discussed in detail in previous responses, *Sommercorn* does not teach such a spaced apart apparatus or arrangement. In particular, Fig. 5 of *Sommercorn* shows instead that each of the holes is located at a distal end of the catheter. Accordingly, *Sommercorn* does not teach or suggest spacing an inlet hole away from a outlet hole in a manner recited in the claims to increase fluid flow coverage.

Applicants respectfully submit that each of the amended claims includes at least the above-described structural difference over *Sommercorn*. Claim 25 is illustrative of the amendments to each of the above-mentioned claims. The amendment to Claim 25 recites a first structural element, namely, a second fluid opening. The second fluid opening is compared structurally to another structural element of the claim, namely, a patient/tube connection location. The patient/tube location is defined clearly in the specification by connection section 16 and the

implantable cuffs 46 and 48. Indeed, Fig. 2 and page 13 of the specification disclose that subcutaneous tissue grows into the implanted cuffs 46, 48 to anchor the catheter 10 to the patient. The patient/tube connection location is clearly defined in the drawings and specification as the points along the catheter or tube at which the cuffs 46 and 48 are placed. A third element of the amendment to the claims is the second fluid opening, e.g. the openings 76, located at the bottom or coiled portion of the catheter in Fig. 1. As seen clearly in Fig. 1, the first hole or holes 56 are located closer to a patient/tube connection point 48 than are the holes 56 located with respect to the second holes 76. *Sommercorn* does not teach or suggest such structure. Indeed, *Sommercorn* appears to teach away from such structure, spacing its holes at the distal end of the catheter.

For at least the foregoing reasons, Applicants respectfully submit that Claim 25 and Claims 26 to 28 that depend from Claim 25, Claim 38 and Claims 39 to 43 that depend from Claim 39, Claim 62 and Claims 63 to 66 and 68 that depend from Claim 62, Claim 69 and Claims 70 and 71 that depend from Claim 69, Claim 95 and Claims 96 and 97 that depend from Claim 95, are each in condition for allowance.

Applicants respectfully submit that the above-identified patent application is now in a condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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